K041026

JUN 2 8 2004

510(k) Summary

Summery prepared: 31 of March 2004

Name and address of Device Manufacturer Submitting 510(k) Notification:

Ambu A/S
Baltorpbakken 13
2750 Ballerup
Denmark

Regulatory Correspondent of Device Manufacturer:

US Agent:

Sanjay Parikh
Technical & Regulatory Affairs Manager

Ambu Inc.
611 N. Hammonds Ferry Road
Linthicum, Maryland 21090-1356

Phone: 800-262-8462 x 1136
Cell Phone: 443 831 9844

Name of device:

Ambu® Blue Sensor MRX, ECG electrode
Catalogue number: MRX-00-S

Classification:

Class II
21 CFR 870.2360 Electrocardiograph electrode.

Intended Use:

The Ambu® Blue Sensor MRX electrode is applied to the surface of the body to transmit the electrical signal at the body surface to a processor in order to produce an electrocardiogram or vectorcardiogram.

The electrode is designed for use in MR environment, therefore the electrode is MR safe, and for X-ray purposes, therefore the electrode is x-ray translucent.
The electrode is for single patient use only.

Predicate Device:

The predicate device used for the purpose of substantial equivalence under this submission was the Blue Sensor SUPAtab ECG Electrode (K983689).
The MRX electrode under this submission is almost identical with the SUPAtab electrode. The most important change is that the metal snap on the SUPAtab electrode has been changed to a snap made from a carbon filled polymer on the MRX electrode.
Both electrodes have an Ag/AgCl sensor material and they consist of the same materials except from the snap.
The SUPAtab electrode is not X-ray translucent and MR safe, however, the MRX electrode is X-ray translucent and MR safe.
Both electrode types meet the AAMI EC12 2000 standard and have a shelf life of 2 years. They are both designed for single patient use only.

Description:

Each electrode consists of a foam material with an adhesive to be mounted on the patient.
The sensor element consists of a foil furnished with a conductive carbon filled polymer snap and a Ag/AgCl sensor point.
On top of the sensor point a sponge is positioned filled with a wet gel that conducts the signal from the patient further on to the electrode. The choise of materials ensures a non-ferromagnetic electrode which makes it x-ray translucent and MR safe.
The electrodes are delivered on a foil sheet with 8 electrodes and 32 electrodes are packed in a laminated foil pouch.
The electrode is non sterile and intended for single use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 8 2004

Ambu, Inc.
c/o Mr. Sanjay Parikh
Technical and Regulatory Affairs Manager
611 North Hammonds Ferry Road
Linthicum, MD 21090

Re: K041026
Trade Name: Ambu® Blue Sensor MRX, ECG Electrode
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph Electrode
Regulatory Class: II (two)
Product Code: DRX
Dated: April 20, 2004
Received: April 21, 2004

Dear Mr. Parikh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Neil R.P. Ogden for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K041026

Device Name: Ambu® Blue Sensor MRX , ECG electrode

Indications For Use:

The MRX disposable ECG electrode is applied to the surface of the body to transmit the electrical signal at the body surface to a processor in order to produce an electrocardiogram or vectorcardiogram.
The electrode is designed for use in MR environment and made for X-ray purposes, therefore the electrode is MR safe and X-ray translucent.
The electrode is made for single patient use only.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for DAZ

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041026

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional format 1-2-96)